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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/914,184	11/16/2001	Yin Hwee Tan	117-363	9483
23117	7590	04/16/2004	EXAMINER	
NIXON & VANDERHYE, PC			KHARE, DEVESH	
1100 N GLEBE ROAD			ART UNIT	
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ARLINGTON, VA 22201-4714			1623	

DATE MAILED: 04/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/914,184	Applicant(s) TAN ET AL.	
	Examiner Devesh Khare	Art Unit 1623	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 22-30,38 and 39 is/are pending in the application.
 4a) Of the above claim(s) 30 and 39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 22-29 and 38 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. ____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>08-23-2007</u> . | 6) <input type="checkbox"/> Other: ____ |

Applicant's election with traverse claims 22-29 and 38 of Group II is acknowledged. The traversal is on the ground(s) that " claims 22-30 and 38-39 which are pending in this application are so linked as to form a single general inventive concept under PCT Rule 13.1". This is not found persuasive because the applicants' claims 22-29 and 38 are drawn to a method of treating a flavivirus or rhabdovirus infection with a composition comprising a nucleoside (class 514 and 536), claims 31-37 are drawn to a method of treating a flavivirus or rhabdovirus infection with an interferon (protein) (class 530) and claims 30 & 39 are drawn to a composition containing an interferon and a nucleoside (514,536 and 530), which would be burdensome to the examiner, as it cannot be assumed that the burden of search under three different classes are the same.

The requirement is still deemed proper and is therefore made FINAL.

The claims which read upon the elected invention are 22-29 and 38.

Claims 31-37 have been cancelled. Claims 30 and 39 have been withdrawn.

An action on the merits of claims 22-29 and 38 is contained herein below.

Minor objections

Claims 1 and 29 are objected to because of the following informalities:

(1) In claim 22, formula (I), "H" is not defined, it should be deleted.

(2) In claim 29, the abbreviations "NSC 382046", "NSC 7364", "NSC 302325", "NSC 184692D" and "NSC 382034" should be preceded in their first occurrence by the specific identity of the entities said abbreviations are intended to represent in the claims.

Thereafter, the use of the abbreviation in the claims will be favorably considered and explicitly understood.

(3) In claim 28, the term "IU" is missing in line 2, before "per mg protein".

Appropriate correction is required.

35 U.S.C. 112, second paragraph rejection

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 22-29 and 38 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

(A) The term "derivatives" is a relative term, which renders the claim 22 indefinite. In the absence of the specific derivatizations to the compound core claimed or the distinct language to describe the structural modifications or the chemical names of derivatized compounds claimed, the identity of said derivatives would be difficult to describe and the metes and bounds of said derivatives applicants regard as the invention cannot be sufficiently determined because they have not been particularly pointed out or distinctly articulated in the claims.

(B) Claim 22 recites "formula (I)". The formula (I) is not defined in terms of points of attachment and location of hetero atoms. It is unclear as to what the applicant intends to encompass by recitation of "formula (I)".

Claims which depend from an indefinite claim which fail to obviate the indefiniteness of the claim from which they depend are also seen to be indefinite and are also rejected for the reasons set forth supra.

35 U.S.C. 103(a) rejection

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 22-29 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Najarian (WO 98/19670) and Sjogren (U.S. Patent 5,380,879).

Claims 22-29 and 38 are drawn to a method of treating a host having a flavivirus or rhabdovirus infection, by administering to the host an effective amounts of an interferon and atleast one compound selected from the group consisting of 5-membered cyclic nucleoside, mycophenolic acid compounds, imidazole derivatives, aminoadamantanes, 2,4-diaminopyrimidines and a quinazoline derivative.

Additional claim limitations claimed include the flavivirus selected from yellow fever virus, kunjin virus, dengue virus, hepatitis C virus, and encephalitis virus; rhabdovirus selected from vesicular stomatitis virus (VSV) and rabies virus; interferon is a human interferon or selected from interferon $\alpha 2$, interferon $\alpha 8$ (specific activity $0.6-1.5 \times 10^9$ IU per mg protein) and interferon β (specific activity $4-8 \times 10^8$ IU per mg protein); and administration to the host in respective amounts.

Najarian teaches a method for treatment of hepatitis C infection with a composition comprising a nucleoside analog, a quinoline antibiotic and an amantadine anti-viral agent including the interferon α (see abstract). The preferred interferon is α , however

interferon β can also be used (page 6, line 1). The said composition can be administered separately or together (page 7, last para.). Najarian discloses the interferon doses in the range of 5-2.5 million units (page 14, Example 1). The nucleoside analogs such as lamivudine, vidarabine and genciclovir; amantadine derivatives; and quinolone antibiotics such as ofloxacin, levofloxacin, ciprofloxacin and norfloxacin are disclosed (page 6, 2nd – 4th para.). The teachings of Najarian does render the use of a composition comprising an interferon and a nucleoside analog, a quinoline antibiotic or an amantadine anti-viral agent to treat flavivirus or rhabdovirus infection prima facie obvious. Najarian differs from the instantly claimed invention that Najarian does not explicitly teaches the use of a composition having an interferon and the mycophenolic acid compounds.

Sjogren teaches the pharmaceutical compositions containing mycophenolic acid compounds useful as anti-viral agents (col. 17, lines 20-30). The mycophenolic acid compounds are represented by the formula I (col.2, line 25).

It would have been obvious to person having ordinary skill in the art at the time the invention to select a composition comprising an interferon and the compounds disclosed in claim 22(b) as the use of the same is well within the purview of the skilled artisan. The skilled artisan would have a reasonable expectation of success in using a composition comprising an interferon and the compounds disclosed in claim 22(b) since Najarian teaches its use in the treatment of viral infection. One would be motivated to use interferon with other anti-viral agents in order to reduce the cost of interferon

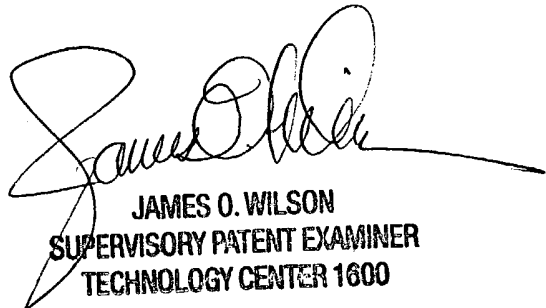
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therapy (Najarian: page 5, 4th para.) or to take advantage of diverse modes of antiviral activity, and to lower the use of potential antiviral-nucleosides which might be toxic.

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Devesh Khare whose telephone number is 571-272-0653. The examiner can normally be reached on Monday to Friday from 8:00 to 4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James O. Wilson, Supervisory Patent Examiner, Art Unit 1623 can be reached at 571-272-0661. The official fax phone numbers for the organization where this application or proceeding is assigned is (703) 308-4556 or 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Devesh Khare, Ph.D.,JD(3Y).
Art Unit 1623
April 2,2004



JAMES O. WILSON
SUPERVISORY PATENT EXAMINER
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